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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,906	01/16/2004	Gennady Nisnevich	1662/607041	1521
26646	7590	02/22/2005	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/759,906	Applicant(s) NISNEVICH ET AL.	
	Examiner Rita J. Desai	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12 , drawn to a process of making 2-butyl-3[2'-(-triphenylmethyl-1H-tetrazol-5-yl-biphenyl-4-yl methyl)]-1,3-diazaspiro[4.4]non-1-ene-4-one classified in class 546, subclass 18.
- II. Claims 13-24, drawn to a process of making 3-(haloaryl)-1,3-diazaspiro[4.4]non-1-ene-4-one , classified in class 546 , subclass 18.
- III. Claim 24 , drawn to a compound
2-butyl-3-(4-bromobenzyl)-1,3- diazaspiro[4.4]non-1-ene-4-one , classified in class 546 subclass 18.
- IV. Claims 25 and 26 , drawn to a process of making
5-phenyl-1-trityl-1H-tetrazole compound , classified in class 549 and various subclasses.
- V. Claims 27-29 , drawn to a process of making
2-(1-trityl-1H-tetrazol-5-yl)phenylboronic acid , classified in class 549 and various , subclasses.
- VI. Claims 30-32 , drawn to another process of making
2-(1-trityl-1H-tetrazol-5-yl)phenylboronic acid , classified in class 549 and various subclasses.

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- VII. Claims 33-35 , drawn to a process of making irbesartan , classified in class 546 and various subclasses.
- VIII. Claim 36 , drawn to another process of making irbesartan , classified in class 546 and various subclasses.
- IX. Claim 37 , drawn to still another process of making irbesartan , classified in class 546 and various subclasses.
- X. Claim 38 , drawn to another process of making irbesartan, classified in class 546 and various subclasses.
- XI. Claim 39 , drawn to another process of making irbesartan , classified in class 546 and various subclasses.
- XII. Claim 40, drawn yet to another process of making irbesartan, classified in class 546 and various subclasses.
- XIII. Claim 41 , drawn to another process of making irbesartan , classified in class 546 and various subclasses.
- XIV. Claim 42 , drawn to a process of making irbesartan , classified in class 546 and various subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions VII-XIV are related as process of making a product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case

The product irbesartan is known in the art and can be made by several other means.

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Inventions I, II, II, IV, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions these inventions are drawn to making different products .

Claim 1 and its dependent claims are drawn to 2-butyl-3[2'-(-triphenylmethyl-1H-tetrazol-5-yl-biphenyl-4-yl methyl)]-1,3-diazaspiro[4.4]non-1-ene-4-one ,
Claim 13 and its dependent claims are drawn to another generic compound 3-(haloaryl)-1,3-diazaspiro[4.4]non-1-ene-4-one.

Claim 24 is a claim to a compound.

Claims 25 and 26 are a process of making a trityl tetrazole compound and claims 27-29 are drawn to another method of making the same as are Claims 30-32 to yet another method of making it. Indicating that there are several ways of making the same compound.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-XIV, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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A telephone call was made to Mr. John Starr on 2/17/05 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If applicant 's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art , the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants preserve their right to file a divisional on the cancelled non-elected subject matter without prejudice in due course.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai
Primary Examiner
Art Unit 1625

RDesai
2/18/05

R.D.
February 18, 2005